AMERICAN
ASSOCIATION
OF BLOOD BANKS

November 30, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 106 1
Rockville MD 20852

Docket No 99D-22 13

Re: Draft Guidance For Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 510(k) Cleared Bloodborne Pathogen Assays to Test Donors

To Whom it May Concern:

The American Association of Blood Banks (AABB) is the professional association for approximately 2200 institutions engaged in the collection and transfusion of blood and blood products, including all American Red Cross blood services regions, independent community blood centers, hospital-based blood banks and transfusion services, and more than 8500 individuals engaged in all aspects of blood collection, processing and transfusion. Our members are responsible for virtually all of the blood collected and more than eighty percent of the blood transfused in this country. The AABB's highest priority is to maintain and enhance the safety of the nation's blood supply.

The AABB appreciates this opportunity to comment on the Draft Guidance for Industry: Revised Recommendations for the Invalidation of Test Results When Using Licensed and 5 10(k) cleared Blood Borne Pathogen Assays to Test Donors. The AABB recognizes this as **a** step by the Food and Drug Administration (FDA) to harmonize its requirements with those of the Clinical Laboratory Improvement Act of 1988 (CLIA). We applaud this effort as it makes the FDA position available to all. However, the guidance does not conform to the scientific principles of laboratory medicine with regard to the use of run controls. It negates the effect of applying the CLIA requirements to donor testing.

We have the following specific comments:

Section III A CLIA Requirements for Control Reagents cites 42 CFR 493. This is a very broad citation and we request that the reference cite the actual section(s) of part 493, which are applicable.

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8101 Glenbrook Road • Bethesda, MD 20814-2749 ♦ Phone: (301) 907-6977 • Fax: (301) 907-6895
Web site: www.aabb.org ♦ Email: aabb@aabb.org

Section III A defines the terms calibrator and control as used by the FDA. It would eliminate confusion if the manufacturers could be required to utilize these same terms in product literature and package inserts.

Section III A requires that "Prior to implementation, additional control reagents should be qualified to minimize possible incompatibilities that may exist with particular test kits." We request clarification of the intent of this recommendation, particularly the term "qualified."

Section III C states "When the test kit package insert instructions have been met, but CLIA control requirements have not been met: 1) any reactive results should not be invalidated and 2) non-reactive results should be invalidated." Although the AABB understands that this has been FDA practice for some time, we do not believe it is an appropriate application of the CLIA requirements. This requirement is not consistent with the accepted scientific principles of the use of run controls in which the entire run is invalidated when the run control(s) is not acceptable. Accepting the reactive results as valid while discarding the non-reactive results as invalid is not logical. A truly reactive sample will continue to be reactive when tested after the cause of the failure of the run controls is investigated and corrected. The AABB requests that this provision be eliminated. Use of run controls as intended by CLIA would provide the same standard for both patient and donor testing, and will not jeopardize the safety of the transfusion recipient.

Section IIIC requires documentation of all incidents of invalidation and specifies the necessary information and investigation to be completed. The AABB agrees that such investigation is essential. However, this section also states "All of these actions should be taken prior to repeat testing of donor samples." While the AABB agrees that this would be desirable, we are concerned at including this level of detail in the guidance and we request that it be deleted.

The AABB especially appreciates the opportunity for early input into FDA decisions before they become final. We endorse issuing draft guidances "for comment only" whenever possible, so that adequate public input can be obtained.

Any questions about these comments should be directed to Kay Gregory, Director Regulatory Affairs at 301-215-6522 or kayg@aabb.org.

Yours truly,

Paul Ness, MD
President